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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,272	04/06/2001	James M. Lipton	259/058	6351
34055	7590	05/05/2004	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/828,272		LIPTON ET AL.	
	Examiner		Art Unit	
	B. Dell Chism		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,10-19 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10-19 and 29-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4 and 7-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to Applicant's paper filed 28 November 2003. Claims 3, 9 and 20-28 are canceled. Claims 1-2, 4-8, 10-19 and 29-38 are pending, with claims 1-2, 4 and 7-8 are under consideration.

Withdrawal of Objections and Rejections

1. The rejections and/or objections made in the prior office action, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 28 November 2003 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. (New) Claims 1-2, 4 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have

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interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claims invention is drawn to pharmaceutical compositions comprising KPV polypeptides of SEQ ID NO:1 and glucocorticoid anti-inflammatories. The specification teaches that the polypeptides of SEQ ID NO:1 has antimicrobial activity.

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The state of the prior art and the predictability or lack thereof in the art: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The art teaches that the use of glucocorticoids carries a detrimental affect toward microbes of skin disorders. (Cutuli *et al.* Journal of Leukocyte Biology, Vol. 67 pages 233-239; cited in previous office action). Cutuli *et al.* teaches, however, that the KPV peptides are not detrimental to microbial control as is with glucocorticoid use. However, there is no indication that the combination of the two compounds into one formulation would adequately control inflammation and microbial loads. Thus, there is no sufficient predictability taught in the art regarding the use of the two in combination in one pharmaceutical formulation.

The amount of direction or guidance present and the presence or absence of working examples: Without adequate teachings found in the art that there is therapeutic efficacy through combined use of glucocorticoids as an anti-inflammatory and KPV as a microbial and anti-inflammatory in one pharmaceutical composition, detailed guidance is required in the specification to enable one of skill in the art to be able to use the claimed polypeptides. This guidance is absent.

The breadth of the claims and the quantity of experimentation needed: Given the teachings of unpredictability which are found in the art regarding the therapeutic efficacy of glucocorticoids used in situations where anti-inflammatories are required in conjunction with anti-microbials like the claimed KPV compounds, and in the absence of sufficient guidance in applicant's disclosure to overcome the teachings of unpredictability which are found in the art, it would require undue experimentation by one of skill in the art to be able to use the claimed invention.

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4. (Withdrawn) Rejection of claims 1 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn as obviated by amendments.

5. (Withdrawn) Rejections of claim 1-4, 7-9, 20-23 and 26-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn as obviated by amendments.

Claim Rejections - 35 USC § 102

6. (Withdrawn) Rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Cutuli *et al.* is withdrawn as obviated by arguments.

Claim Rejections - 35 USC § 103

7. (Withdrawn) Rejection of claims 1-4 and 7-9 under 35 U.S.C. 103(a) is withdrawn as obviated by applicants' arguments.

Double Patenting

8. (Maintained) The rejection of claims 1-2, 4 and 7-8 as provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7 and 10-11 of copending Application No. 10/023,287 ('287) is maintained.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons previously stated. Applicants' arguments that the '287 compounds are for shampoo and veterinary uses is not relevant when the present invention is drawn to a compound comprising the compounds as that of the co-pending application. The Cutuli *et al.* reference of the previous office action is not required in the present double patenting rejection. The claims were amended to encompass an intended use (i.e., treatment of psoriatic disorders and contact dermatitis), however, this intended use limitation is not enough to obviate the rejection.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed. Claims 1-2, 4 and 7-8 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


B. Dell Chism


CHRISTOPHER R. TATE
PRIMARY EXAMINER